

WHAT IS CLAIMED IS:

- 5           1. A stable suspension of a biologically active protein suited for aerosol delivery to the respiratory tract of a patient in need of treatment comprising particles of said protein suspended in ethanol.
- 10           2. A stable suspension according to claim 1 wherein said ethanol is substantially anhydrous.
3. A stable suspension according to claim 1 wherein said ethanol contains less than 5% water.
- 15           4. A stable suspension according to claim 1 wherein said ethanol contains less than 3% water.
- ✓           5. A stable suspension according to claim 1 wherein said biologically active protein is selected from the group comprising enzymes, antibodies, 20 antigens, hormones and cytokines.
- ✓           6. A stable suspension according to claim 5 wherein said *biologically* therapeutically active protein is a hormone.
- Sub A2 ✓ 25           7. A stable suspension according to claim 6 wherein said therapeutically active protein is ~~insulin~~.
8. A stable suspension according to claim 5 wherein said *biologically* therapeutically active protein is a cytokine.
- 30           9. A stable suspension according to claim 5 wherein said therapeutically active protein is ~~Factor VIII~~.
- Sub A3 ✓

✓ 10. A stable suspension according to claim 1 wherein ~~the~~ particle size of said protein is from about 0.01  $\mu$  to about 10.0  $\mu$ .

11. A stable suspension according to claim 10 wherein the particle  
5 size of said protein is from about 5.0  $\mu$  to about 10.0  $\mu$ .

12. A stable suspension according to claim 11 wherein the particle size of said protein is from about 0.01  $\mu$  to about 3.0  $\mu$ .

10 13. A stable suspension according to claim 1 wherein said suspension contains up to 20% V/V of a formulation additive.

14. A stable suspension according to claim 13 wherein said suspension formulation additive is selected from the group consisting of  
15 glycerol, propylene glycol and polyethylene glycol.

15 15. A stable suspension according to claim 1 wherein said suspension contains from about 0.5% to about 5.0% of a pharmaceutically acceptable excipient.

20 16. A stable suspension of insulin useful for aerosol delivery to the lungs of a patient in need of treatment comprising particles of a pharmaceutically effective amount of insulin suspended in ethanol.

25 17. A stable suspension according to claim 16 wherein said insulin is present in the suspension at a concentration of from about 1.0 mg/ml to about 200.0 mg/ml of suspension.

✓ 30 18. A stable suspension according to claim 16 wherein ~~the~~ particle size of said insulin is from about 0.01  $\mu$  to about 5.0  $\mu$ .

19. A stable suspension according to claim 16 wherein said suspension contains up to 20% V/V of a formulation additive.

20. A stable suspension according to claim 19 wherein said  
✓ ~~suspension~~ formulation additive is selected from the group consisting of  
glycerol, propylene glycol and polyethylene glycol.

5        21. A stable suspension according to claim 16 wherein said  
suspension contains from about 0.5% to about 5.0% of a pharmaceutically  
acceptable excipient.

10        22. A method of delivering a therapeutically effective amount of a  
protein to the respiratory tract of a patient in need of treatment which  
comprises producing an aerosol of a stable liquid suspension of said protein  
using an electrostatic spraying means wherein said liquid suspension  
comprises particles of said protein suspended in ethanol. *and administering said aerosol  
to said patient*

15        23. A method according to claim 22 wherein said protein is selected  
from the group comprising enzymes, antibodies, antigens, hormones and  
cytokines.

20        24. A method according to claim 23 wherein said therapeutically active  
protein is a hormone.

25        25. A method according to claim 24 wherein said hormone is insulin.

26. A method according to claim 23 wherein said protein is a cytokine.

27. A method according to claim 26 wherein said cytokine is Factor  
VIII.

✓ 30        28. A method according to claim 22 wherein the particle size of said  
protein is from about 0.01  $\mu$  to about 10.0  $\mu$ .

29. A method according to claim 28 wherein the particle size of said  
protein is from about 5.0  $\mu$  to about 10.0  $\mu$ .

30. A method according to claim 29 wherein the particle size of said protein is from about 0.01  $\mu$  to about 3.0  $\mu$ .

5 31. A stable suspension according to claim 22 wherein said suspension contains up to 20% V/V of a formulation additive.

10 32. A stable suspension according to claim 31 wherein said suspension formulation additive is selected from the group consisting of glycerol, propylene glycol and polyethylene glycol.

15 33. A stable suspension according to claim 22 wherein said suspension contains from about 0.5% to about 5.0% of a pharmaceutically acceptable excipient.